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Office Action Summary

Application No.	Applicant(s)
09/887,625	Makino
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 4, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Specification

1. Claim 1 has been amended.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mathies et al. (U.S. Patent 6,361,671 B1) (March 26, 2002).

Mathies et al teach a method of detecting nucleic acid fragments in plural samples (Abstract) which comprises the steps of:

a) attaching an electroconductive label to nucleic acid fragments in one sample and attaching another electroconductive label to nucleic acid fragments in another sample, the former electroconductive label and the latter electroconductive label having oxidation-reduction potentials differing from each other (Claims 8, and 26-42 and Column 10, lines 14-26);

b) preparing a mixture of the samples containing nucleic acid fragments to which electroconductive labels are attached (Claims 8, and 26-42 and);

c) bringing the mixture into contact with an elctroconductive microarray having plural electrodes onto which probe molecules complementary to the nucleic acid fragments are fixed, so that hybridization between the nucleic acid fragments having elctroconductive labels and the probe molecules on the elctroconductive microarray can proceed to form hybrid structures on the electrodes (Column 8, line 55 to Column 9, line 6 and Column 10, lines 46-55 and Figure 1);

d) applying to the electrode an electric potential corresponding to the oxidation-reduction potential of the former elctroconductive label and detecting on the electrode an electric current flowing along the hybrid-structure (Figures 4-5 and 8-9 and Claim 41);

e) applying to the electrode an electric potential corresponding to the oxidation-reduction potential of the latter elctroconductive label and detecting on the electrode an electric current flowing along the hybrid-structure (Figures 4-5 and 8-9)

and

f) comparing the electric current detected in the former detecting procedure and the electric current detected in the latter detecting procedure to obtain a ratio of the content of the nucleic acid fragments in each sample (Figures 4-5 and 8-9).

Mathies et al teach a method, wherein the probe molecules are nucleic acid fragments (Claims 26-42 and column 10, line 14 to column 11, line 45).

Mathies et al teach a method, wherein the probe molecules are peptide nucleic acid fragments (Column 11, lines 22-26 and Column 12, lines 29-36).

Mathies et al teach a method, wherein the oxidation-reduction potential of the latter elctroconductive label differs from the oxidation-reduction potential of the former elctroconductive label by at least 50 mV (Figures 4A and 4B and Column 7, lines 60-63).

Mathies et al teach a method, wherein the oxidation-reduction potential of the former elctroconductive label and the oxidation-reduction potential of the latter elctroconductive label both are in the range of 0 to 800 mV (Figures 4A and 4B and Column 7, lines 60-63).

Mathies et al teach a method, wherein the detection of electric current on the electrodes are conducted by differential pulse voltamography (Figures 4A and 4B and Column 8, lines 30-40).

Mathies et al inherently teach a method, wherein one sample is obtained from normal cells and another sample is obtained from abnormal cells corresponding to the normal cells (Claims 41 and 42 and Column 3, lines 38-53).

Mathies et al inherently teach a method, wherein one sample is obtained from wild strain and another sample is mutant thereof (Claims 41 and 42 and Column 3, lines 38-53). This inherence is deduced from the fact that polymorphisms and mutations are detected compared to normal cells or wild strain.

Response to Amendment

4. In response to amendment, 112(second paragraph) rejection has been withdrawn. However, 102(e) rejection has been maintained properly.

Response to Arguments

5. Applicant's arguments filed on November 4, 2002 have been fully considered but they are not persuasive. Applicant argues that 102(e) rejection should be withdrawn because cited reference of Mathies et al teaches an extra step of chromatography or electrophoresis of nucleic acid before its detection, which is not required by the claimed invention. This argument is not persuasive. The open language "comprises the steps of" of claim 1 allows any other step(s) or materials(s) to be added in any order with the steps of claimed invention. Therefore, the rejection is proper.

Applicant also argues that group of probe molecules and hybridization of nucleic acids is not taught by Mathies et al. This argument is not persuasive. Applicant argues that Mathies reference does not teach the group of probe molecules and hybridization of nucleic acids of the claimed invention. Applicant argues that the word "group of probe molecules and hybridization of nucleic acids" was not found in Mathies reference. Applicant argues that because Mathies has a preferred embodiment of detection by redox molecules, Mathies is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or

nonpreferred embodiments. In re Susi,169 USPQ 423 (CCPA 1971)." MPEP 2123 also states " A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories , 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Mathies has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Mathies reference uses microfabricated capillary to detect redox-active labels, the property of group of probe molecules and hybridization of nucleic acids is inherently present in this chemically and structurally identical molecule. For example, Mathies teaches that such multiplex redox labeling and electrochemical detection can be used in conjunction with genotyping and SNP analysis all of which use primers for labeling and determining genetic variation (Column 6, lines 25-36). It is also clear from Figure 9 of Mathies that PCR products are determined by hybridizing with primers. Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater,* 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, any nucleic acid primers under any suitable conditions can be used for gel hybridization.

Therefore, 102(e) rejection made in the first office action is hereby properly maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

November 19, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600